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Saunders Batunkyi

*Philadelphia College of Osteopathic Medicine, [saundersba@pcom.edu](mailto:saundersba@pcom.edu)*

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**Will the use of fiber be as effective as laxatives in relieving constipation in the geriatric population?**

Saunders Batunkyi, PA-S

A SELECTIVE EVIDENCE BASED REVIEW

Department of Physician Assistant  
Philadelphia College of Osteopathic Medicine  
Philadelphia, Pennsylvania

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## ABSTRACT

**OBJECTIVE:** The objective of this selective EBM review is to determine whether or not the use of fiber can be as effective as laxatives in relieving constipation in the geriatric population.

**STUDY DESIGN:** Review of three journals published in English in peer-reviewed journals.

**DATA SOURCES:** Two randomized controlled trials and one parallel interventional trial investigating the effectiveness of supplemental dietary fiber in managing constipation in elderly populations that are presently reliant on prescription laxatives.

**OUTCOMES (S) MEASURED:** The outcomes were measured by the frequency of defecation, ease of bowel movement, patient discomfort, patient well being, and undesired effects of laxative use.

**RESULTS:** The studies demonstrated that the use of supplemental dietary fiber is an effective alternative to laxatives in managing constipation in the elderly.

**CONCLUSIONS:** Supplemental dietary fiber is an effective alternative to prescription laxatives in the management of constipation in the geriatric population with the correct patient population in mind.

**KEY WORDS:** Fiber, laxative, constipation, geriatric, elderly.

## INTRODUCTION

Constipation is a common problem in the geriatric population. Treatment of constipation may include adding supplemental dietary fiber or use of pharmacologic laxatives, however dietary fiber can be effective and have fewer side effects as compared to laxatives. According to the Rome II criteria constipation is defined when at least two of the six criteria are present for at least 12 weeks in the past 12 months. The criteria are 1) straining in at least 25% of bowel movements 2) pellet-like or hard stool in 25% of bowel movements 3) sensation of incomplete evacuation in at least 25% of bowel movements 4) sensing an anal blockage in at least 25% of bowel movements 5) the need to use manual maneuvers to aid stooling in at 25% of the time and 6) having fewer than three bowel movements per week.<sup>1</sup> From a patients perspective the complaints range from needing to strain, having fewer bowel movements, or unsuccessful stooling. In the elderly population it is estimated that up to 30% suffer from chronic constipation and an estimated 50% to 70% of nursing home residents suffer from constipation.<sup>4,5</sup> It also estimated that \$500 million per year is spent in the United States on laxatives for the management of constipation, and constipation accounts for 2.5 million physician office visits annually.<sup>3</sup>

Constipation is not a physiologic consequence of aging, but is associated with low intake of dietary fiber or fluid, physical inactivity, side effects of medication, and from medical and psychiatric conditions. The usual management of constipation includes both non-pharmacologic and pharmacologic treatments. Non-pharmacologic treatments include bowel training; increase fluid intake, regular exercise, and dietary fiber. Pharmacologic treatments of constipation are the standard of care in geriatrics and include bulk, osmotic, and stimulant laxatives. Laxatives act on physiologic function of the intestine such as preventing the colon from reabsorbing water and

disturb the physiologic and biochemical interaction between content of the gut, epithelium, and the bacterial flora.

## OBJECTIVE

The objective of this selective EBM review is to determine whether supplemental dietary fiber is as effective as laxatives in managing constipation in the geriatric population.

## METHODS

The articles selected for this selective evidence based medicine (EBM) review have met specific requirements to investigate the stated objective. The articles consisted of two randomized control trials and a parallel interventional trial. The articles were selected using the key words: fiber, laxative, constipation, geriatric, and elderly. The research was conducted in PubMed by the author of this selective EBM review and all articles being published in English and published in peer-reviewed journals. Two randomized controlled trials and a controlled parallel interventional trial was selected that date no later than 1996. Chosen articles targeted geriatric patients and included patient oriented outcomes (POEMS). Articles were excluded if they were systematic reviews, non-patient oriented outcomes and non-geriatric population. Hale et al reported statistic Mean (SD) and p-value, Sturtzel et al resported statistics in Mean ( $\pm$ SD) + (Range) and p-value, and Wisten reported statistics in 95% confidence interval and p-value.

The Hale's subjects resided in a long term care facility with ages 65 to 100. He compared the effectiveness of adding 2 tablespoons Beverley-Travis natural fiber laxative mixture to meals to prescribed laxatives over an 8-week trial. The initial 4 weeks involved a pre-intervention period in which no changes were made to current constipation management and baseline data was collected. During the second 4 weeks the groups were randomized into a control and study group. The study group ceased use of prescribed laxatives and received 2

tablespoons of the Beverly-Travis natural fiber laxative twice a day. Beverly-Travis natural laxative is a grinded mixture of raisins, pitted prunes, figs, dates, currants, and prune concentrate which contains 1.4 g fiber.

Sturtzel's subjects resided in geriatric ward and were ages 57 to 100 with 15 persons with a mean age of 86 in the fiber group and 15 persons with a mean age of 84.6 in the control group. The intervention was the addition of 7-8 g of an oat-bran fiber product that contained 8.3g of non-digestible fermentable fiber and 9.7g of non-digestible non-fermentable fiber per 100g to their food over a 12 week course. Both groups received the same habitual menu and continued laxative use.

Wisten et al included subjects from a geriatric hospital ward with a mean age of 74.9 in the study group and 78.4 in the control group. The intervention was the introduction of a porridge containing 7.5 grams of fiber per serving at breakfast compared to the control group served a standard breakfast over a 2 week period. The outcomes measured were the frequency of defecation, ease of bowel movement, patient discomfort.

Each article had its own inclusion and exclusion requirements for their study. Hale et al inclusion criteria required that the subjects had the ability to orally ingest soft foods and fluids, history of constipation, and were currently being treated with prescription laxatives. Subjects were excluded if they did not meet these criteria. Sturtzel et al included patients who ingested food orally and were on prescribed laxative therapy. Exclusion included parental and enteral feeding, surgeries of the gastrointestinal tract, use of medications that shorten or lengthen passage through the intestine, risk of aspiration, and dysphagia. Wisten et al included subjects from the geriatric ward with diagnoses of stroke, surgery for degenerative joint disease and

Parkinson's disease. Patients were excluded if they suffered from aphasia, dysphagia, dementia, or were in very poor general condition. The demographics of the articles are shown in Table 1.

Table 1: Demographics of included studies							
Study	Type	# pts	Age	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Hale <sup>2</sup> , 2007	RCT	45	65-100	Admission to the study site, ability to digest soft foods and fluid orally, positive history of constipation, and currently being treated with laxatives.	N/A	11	2 tablespoon of Beverly-Travis natural laxative mixture BID (fiber)
Sturtzel <sup>5</sup> , 2009	Controlled parallel intervention trial	30	57-100	Oral food intake and laxative therapy	Parenteral and enteral feeding. Surgeries in the gastrointestinal tract. Use of meds that shorten or lengthen passage through the intestine. Risk of aspiration. Dysphagia	0	7-8 grams oat-bran fiber daily
Wisten <sup>6</sup> , 2005	RTC	20	Test subjects mean age of 74.9; control subjects mean age 78.4	Patients of a rehabilitation hospital diagnosed with stroke, DJD, Parkinson's disease and immobilized patients.	Patients with aphasia, dysphagia, dementia, and poor general condition.	0	Pajala porridge

## OUTCOMES MEASURED

Each study had a different criterion to demonstrate the effectiveness of the intervention. In Hale et al study the registered nursing staff collected data on the daily bowel movements on each shift over an 8 week period. Bowel movement data was placed into 3 groups: normal pattern, constipation, and diarrhea. Normal bowel movement was considered 2 or more movements without diarrhea within a 7 day period. Hale et al considered 3 or more loose watery movements within 24 hours as diarrhea. Constipation was considered as less than 2 bowel movements within 7 days.<sup>2</sup>

Sturtzel et al relied on the nursing staff to record laxative use and bowel movement frequency. Recordings were taken after day 10 of the 84 day study. Sturtzel was present during the lunch and coffee time of the participants. Compliance of fiber supplement was maintained by adjusting the meal wishes of the participants.<sup>5</sup>

In Wisten et al study, the nursing staff recorded stool frequency, laxative therapy use, and the patient's discomfort using a visual analogue scale. Patients also recorded their abdominal discomfort (pain, flatulence, etc.) on a visual analogue scale. The scale measured from 1 to 10 with 1 being no abdominal discomfort.<sup>6</sup>

## RESULT

Hale found that during the initial 4-week pre-intervention period there was no difference in number of bowel movements between the study and control group. The study began with 45 participants but 34 participants finished the 8-week study. The reduction in participant size was due to 1 resident being discharged, 3 randomized residents in the control group who were administered Beverly-Travis natural laxative incorrectly, and 4 members of the treatment group had concerns over the use of the Beverly-Travis natural laxative. The 18 member control group



had an average of 17.2 bowel movements in the first 4 weeks and 19.2 movements in the second 4 weeks ( $p = 0.195$ ). The 16 member study group had 15.5 bowel movements during the pre-intervention 4 weeks and 22.2 movements during the subsequent intervention 4 weeks. This was statistically significant to Hale et al ( $p = 0.007$ ). In the fiber laxative group one subject did have the dosage reduced to 30mL every other day due to loose stool, and another patient had to increase the dosage to 30mL three times a day to avoid constipation. The results of Hale's study are show in Table 2.<sup>2</sup>

Pre-intervention Weeks	Control Group Mean (SD) n=18	Treatment Group Mean (SD) n=16
1	4.2 (2.2)	4.1 (2.4)
2	4.9 (2.8)	4.4 (2.8)
3	.9 (2.5)	3.4 (1.9)
4*	.2 (3.0)	3.6 (3.1)
Total	17.2	15.5
Intervention Weeks		
5	5.1 (3.1)	5.8 (2.0)
6	5.2 (2.9)	6.6 (3.2)
7	4.3 (2.8)	5.0 (2.4)
8	4.6 (2.0)	4.8 (2.8)
Total	19.2	22.2*

\* $P < 0.05$

In Sturtzel's study the interventional group added an additional 5.1 g of fiber to their diet over the 84 day course. Sturtzel found that there was a reduction in the use of polyethylene glycol and diphenylmethane derived laxatives by 59% in the 15 member study group. This was statistically significant to Sturtzel et al with  $p < 0.001$ . In contrast, there was an increase in laxative use in the 15 member control group by 8% ( $p = 0.218$ ). This data is reflected in Table 3. Defecation frequency remained constant between both the study and control group. The bowel movement frequency was 3.3/week for the study group ( $p = 0.491$ ) and 3.2/week in the control group ( $p = 0.770$ ).<sup>5</sup>

Table 3: Laxative Use (Mean (SD) of Laxative units used/patient/period) in the Fiber and Control Group		
	Fiber Group Mean ( $\pm$ SD) + (Range)	Control Group Mean ( $\pm$ SD) + (Range)
Days 07-33	13.07 ( $\pm$ 5.78)	12.87 ( $\pm$ 8.14)
Days 34-59	7.27 ( $\pm$ 3.91)	12.33 ( $\pm$ 8.21)
Days 60-84	5.40 ( $\pm$ 4.22)	13.87 ( $\pm$ 7.40)
P-value	P < 0.001	P = 0.218

Wisten found that there were more days with bowel movements without laxative use in the porridge fiber group. The study group had a daily defecation without laxatives of 76% or 10.7/14 days. In comparison, the control group had a daily defecation without laxatives of 23% or days 3.3/14 ( $p = 0.003$ ). They observed no significant difference in the number of days without defecation between the two groups ( $p = 0.06$ ). The 2.5/14 days for the study and 5.6/14 days for the control group. In addition they found the porridge group had less abdominal discomfort and reduction in laxative use. Patient discomfort on a 1 to 10 scale was lower in the interventional group with an average rating of 2.5 and 5.6 in the control group which was statistically significant ( $p = 0.008$ ). Wisten's statistical results are summarized in Table 4.<sup>6</sup>

Table 4: Single factor analysis of differences in the fiber porridge and non-fiber groups			
	Fiber Group	Control group	P-value
Number of days with defecation without laxatives (SD)	10.7 (4.1)	3.2 (5.5)	0.003
Number of days with defecation and osmotic/stimulant laxatives (SD)	0.8 (1.9)	5.2 (4.4)	0.009
Number of days without defecation (SD)	2.5 (2.8)	5.6 (4.0)	0.06
Patient abdominal discomfort (SD)	2.5 (1.8)	5.6 (2.6)	0.008

Wisten calculated for immobilization, age, sex and use of medications that cause constipation as a side effect. Wisten et al found only the fiber containing porridge significantly

predicted more days with defecation without laxatives, less patient discomfort and fewer doses of laxatives in his subjects. In addition, the coefficient for testing for days without defecation was not statistically significant. Wisten used a chi-square analysis to test the differences in the variables of immobilization, analgesic use, and patient sex. The continuous data between the porridge fiber group and the non-porridge group: patient discomfort, days without laxative use, and days without defecation were tested with Student's t-test. The result of the confidence intervals and p-values of the multifactor analysis are reflected in Table 5.<sup>6</sup>

Table 5: Multifactor analysis of the effects of fiber in the prevention of constipation						
	Days without laxatives			Patient discomfort		
Factor	Coefficient	95% CI	p-value	Coefficient	95% CI	p-value
Immobilization	-0.02	-6.3 to 6.3	0.995	0.12	-3.0 to 3.3	0.936
Drugs with constipation side effect	-5.18	-12.6 to 2.2	0.156	1.23	-2.4 to 4.8	0.469
Age	0.02	-0.27 to 0.31	0.887	-0.01	-0.16 to 0.14	0.884
Sex	-4.32	-11.5 to 2.8	0.215	1.27	-2.2 to 4.8	0.444
Porridge use	7.91	2.9 to 13.0	0.005	-3.28	-5.9 to -0.69	0.017
	Days without defecation			Days with laxatives		
Factor	Coefficient	95% CI	p-value	Coefficient	95% CI	p-value
Immobilization	-0.45	-5.3 to 4.4	0.847	0.47	-3.5 to 4.5	0.806
Drugs with constipation side effect	0.62	-5.1 to 6.3	0.820	4.6	-0.12 to 9.2	0.055
Age	-0.01	-0.24 to 0.21	0.914	-0.01	-0.19 to 0.18	0.925
Sex	-0.45	-6.0 to 5.1	0.863	4.8	0.26 to 9.3	0.040
Porridge use	-3.1	-7.0 to 0.8	0.113	-4.8	-8.0 to -1.6	0.006

CI=confidence interval

## DISCUSSION

The Beverly-Travis natural fiber laxative study demonstrated that a dietary fiber can be as effective prescription laxatives in the relief of constipation in the geriatric population. Their study selected an elderly population in a long term care center with history of constipation and

was currently being treated with prescription laxatives. During the 4 interventional weeks the study group had more bowel movements. The only adverse events reported by Hale were the two patients mentioned earlier with diarrhea and constipation respectively. Tolerability of the fiber laxative was maintained throughout the test group after fiber laxative dose adjustments were made, and Hale reports no other incidences. This leans favorably for the use of natural fiber laxative over prescribed laxative by Hale's study.<sup>2</sup>

The limitation of the Hale et al study is that it did not give data on the prescription laxatives that the fiber laxative was compared against. The variability of the amount and types of prescription laxative could have swayed the result in favor of the Beverly-Travis fiber laxative.

Sturtzel et al demonstrated that the addition of a dietary fiber can be as effective in managing constipation. The study group was able to defecate with a reduction in laxative use when compared to the control group. This is beneficial to the patient because they can avoid potential side effects of laxative use. Sturtzel et al reported the oat bran fiber was well tolerated and a high compliance was achieved and there was no attrition of either group.<sup>5</sup>

Wisten et al demonstrated the fiber rich porridge resulted in improved bowel movements, patient comfort, and also lowered the use of prescription laxatives when compared to the control population. In addition the study also addressed the subjective quality of patient discomfort and found that patients in the porridge fiber group suffered less abdominal discomfort as compared to the control group. This may be a benefit but patient comfort can only be applied to the porridge in the context of the articles reviewed and this selective EBM review cannot state that all dietary fiber supplements will have this benefit over prescription laxatives.

The weakness of all the studies is that they were not blinded. The participants were aware of the intervention if they were sound of mind, and the caregivers were also aware of which patients were receiving the intervention. Another limitation is that the participants in the studies were residents or patients of a LTC facility or hospital ward and represent a subset of the geriatric population. The relatively small study size of each study and of variation in duration of each study is another limitation. For example Wisten had only 20 participants and a 2 week study without a pre-intervention period to collect data. In contrast, Sturtzel et al study had 30 participants and ran for 84 days. In terms of the article search for this selective EBM review, the search yielded a non-consistent dietary fiber intervention. This can be viewed as a limitation in answering the objective of this review or as strength, since different sources of fiber yielded a favorable outcome according to each authors.

## CONCLUSION

Based on the articles selected for this selective EBM review supplemental dietary fiber can be as effective as laxatives in relieving constipation in the geriatric population, but with the correct patient in mind. Each study used a different dietary fiber source with favorable outcomes, but each study does have limitations and short coming to answer the question in a blanket statement. Perhaps a larger double blinded multicenter study that looks at specific subsets of the geriatric population with a controlled intervention may better investigate the question.

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